

Scancell Holdings Plc

("Scancell" or the "Company")

Final Results for the year ended 30 April 2017

Landmark five year survival achieved in resected SCIB1 patients

Emerging pipeline of three products across five cancer indications

Scancell Holdings plc, ('Group' or the 'Company') the developer of novel immunotherapies for the treatment of cancer, announces results for the year ended 30 April 2017.

Highlights:

- Strong survival data for patients with Stage III/IV malignant melanoma on SCIB1 Phase 1/2 clinical trial
 - o 18 of 20 patients with resected disease remain alive, survival well beyond established norms
 - Of the 16 resected patients who received a 2-4mg dose of SCIB1, seven patients have now survived for five years since starting treatment and only six patients have had recurrence of their disease, of whom, two have died
 - Final Clinical Study Report completed in December 2016 which included safety, immunology and clinical data from patients with Stage III/IV melanoma up to 29 October 2015
- Investigational New Drug (IND) application for SCIB1 Phase 2 checkpoint inhibitor combination study expected to be submitted in early 2018, with patient enrolment planned for 2018
- Continued good progress in development of Modi-1, our lead product from the Moditope® platform
 - Ultra-efficient linked adjuvant identified that works at up to 100-fold lower doses than could be achieved previously
 - Aiming to file a Clinical Trial Application (CTA) in the UK for the planned Phase 1/2 clinical trial in breast cancer, ovarian cancer and sarcoma in 2018
 - Early feedback from the European Patent Office suggests that broad patent claims for the Moditope® platform may be allowable
- Opening of new offices in San Diego to support the Company's US growth plans, and in Oxford for its UK corporate and development activities
- Loss for year of £3.5m (2016: loss £2.6m)
- Group cash balance at 30 April 2017 was £2.7m (30 April 2016: £6.5m)

Post Period Highlights:

- Raised £4.7m in a placing of new ordinary shares
 - Funds to be used to initiate the clinical development of Modi-1 and to continue to support the ImmunoBody® platform pipeline
 - Patent granted in Europe for Scancell's DNA ImmunoBody® technology
 - Counterparts to this patent have already been granted in the US, Australia and Japan

Dr Richard Goodfellow, CEO of Scancell, said:

"We have made further significant progress during the course of the past year on the development of our ImmunoBody® and Moditope® platforms. We continue to report strong survival data in patients with Stage III/IV melanoma from our SCIB1 Phase 1/2 clinical trial, with survival times now exceeding five years in resected patients.

Moditope® is also progressing well with the identification of a new linked adjuvant for the first Modi-1 clinical trial in the UK in patients with breast cancer, ovarian cancer and sarcoma which is expected to increase the potency of the product up to 100-fold.



We are continuing to explore a number of funding options to ensure that we have the resources to progress these programmes through their next phase and the Board believes that this funding could be best achieved following the execution of one or more partnerships on the ImmunoBody® or Moditope® platforms, on which significant progress has been made since the year end."

For Further Information:

Scancell Holdings Plc

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About Scancell

Scancell is developing novel immunotherapies for the treatment of cancer based on its ImmunoBody® and Moditope® technology platforms.

Scancell's first ImmunoBody®, SCIB1 is being developed for the treatment of melanoma. Data from the Phase 1/2 clinical trial demonstrate that SCIB1, when used as monotherapy, has a marked effect on tumour load, produces a melanoma-specific immune response and highly encouraging survival trend without serious side effects. In patients with resected disease there is increasing evidence to suggest that SCIB1 may delay or prevent disease recurrence.

Scancell's ImmunoBody® vaccines target dendritic cells and stimulate both parts of the cellular immune system: the helper cell system where inflammation is stimulated at the tumour site and the cytotoxic T-lymphocyte or CTL response where immune system cells are primed to recognise and kill specific cells.

Pre-clinical data on a combination of SCIB1 or SCIB2 and checkpoint inhibition (blockade of the PD-1 or CTLA-4 immune checkpoint pathways) have shown enhanced tumour destruction and significantly longer survival times than when either treatment was used alone.

Scancell has also identified and patented a series of modified epitopes that stimulate the production of killer CD4+ T cells that destroy tumours without toxicity. The Directors believe that the Moditope® platform could play a major role in the development of safe and effective cancer immunotherapies in the future.



CHAIRMAN'S STATEMENT

I am pleased to report on the final results of Scancell Holdings plc ("Group" or the "Company") for the year ended 30 April 2017.

During the year, the Group announced that the Clinical Study Report (CSR) on the SCIB1 Phase 1/2 clinical trial in patients with Stage III/IV malignant melanoma had been completed on schedule. As of August 2017, 18 out of the 20 patients with resected disease remain alive and seven have now survived for more than five years. The manufacture of a new batch of SCIB1 has been completed and released for clinical use.

The Company has been making good progress in compiling the Investigational New Drug (IND) application to the FDA for the SCIB1 checkpoint inhibitor combination study in the US. The request by the FDA for Ichor to provide data on its second generation TriGrid electroporation device has resulted in a short delay to our IND submission. However, we expect that this will be submitted in early 2018.

The Company has made substantial progress on the identification of an ultra-efficient adjuvant for Modi-1. This adjuvant, which will be linked to the Moditope® peptides before injection, stimulates potent cancer killing T cells at up to 100-fold lower doses than could be achieved previously. The Company is currently undertaking process development work on the manufacture of Modi-1 conjugated to the adjuvant with the aim of filing a Clinical Trial Application (CTA) in the UK for the planned Phase 1/2 clinical trial in 2018.

The Board has made significant progress in partnering discussions on both its ImmunoBody® and Moditope® platform product candidates, and progress has continued to be very encouraging since the year end.

Since the year end, the Group has raised net proceeds of £4.7m from a firm placing of shares. These additional funds will be used to support the Company's clinical development pipeline arising from the ImmunoBody® platform and initiate clinical development of the first product from the Moditope® platform, Modi-1.

Two Powerful Proprietary Platforms

Scancell is exploiting the unrivalled potential of the human immune system to develop therapeutics that seek out and eliminate cancer using our two proprietary immuno-oncology platforms.

ImmunoBody®

Scancell's potent innovative DNA-based ImmunoBody® therapies generate ultra-high avidity T cell responses that target and eliminate cancerous tumours. Although there have been some successes, therapeutic cancer vaccine development has been hampered by high failure rates that can in large measure be attributed to a failure to trigger the induction of the high avidity multi-targeted anti-tumour T cell responses that are required to control the disease. Pre-clinical studies have confirmed that the ImmunoBody® platform delivers killer T cell responses that are superior in magnitude to those generated by current cancer vaccines in development. Moreover, different T cell epitopes can be grafted into the framework allowing for rapid customisation for the targeting of multiple tumour types.

SCIB1 melanoma vaccine

During the year we reported that the final CSR on the SCIB1 Phase 1/2 clinical trial in patients with Stage III/IV malignant melanoma was completed in December 2016. The CSR includes safety, immunology and clinical data from all patients with Stage III/IV melanoma up to 29 October 2015, the date of the last patient's final dose in the main part of the study.

SCIB1 is continuing to deliver robust survival data, with a total of seven patients with resected disease surviving for more than five years, well beyond the established norms. Of the 16 resected Stage III/IV patients who received 2-4 mg doses of SCIB1, only six patients have had recurrence of their disease, of whom, two have died. One patient with unresected disease has also survived for more than five years since starting treatment with SCIB1, despite disease progression. Two of four resected patients who received 8 mg doses of SCIB1 have experienced disease recurrence although none have died.

In last year's accounts, I reported that following quality control analysis the Company had suspended dosing with the existing clinical supplies of SCIB1 as the stored drug product was no longer within its original specification. The Company subsequently signed an agreement with a new GMP manufacturer to supply



materials and the new batch of SCIB1 has now been manufactured successfully and was released for clinical use in August 2017.

As a result of the problems with clinical supplies, Scancell suspended its treatment continuation programme in June 2016. Of the eight patients who were previously receiving long term continuation treatment at the time, three have experienced a recurrence of their melanoma. The other five patients remain disease-free. Following a review with our clinical investigators, it was decided not to continue the SCIB1 long term continuation treatment in the five remaining disease-free patients. These patients have received between six and 17 doses of SCIB1 prior to a dosing holiday of more than 15 months. The Company believes that the effects of any further dosing would therefore be difficult to interpret and to justify to the regulatory authorities.

The proposed SCIB1 checkpoint inhibitor combination Phase 2 study in the US will utilise Ichor's latest TriGrid 2.0 clinical device. At the Company's pre-IND meeting in February 2017, the FDA recommended that the technical data from Ichor regarding the new device should be submitted 30-60 days prior to Scancell's own FDA submission. Ichor now anticipates making its Master File submission in mid-November, which will mean a short delay in the submission of the IND application for SCIB1 to the FDA. However, we expect that this will be completed in early 2018 and patient enrolment will still commence in 2018, subject to the availability of sufficient funding for the trial.

Post year end, we were pleased to announce that a patent for Scancell's DNA ImmunoBody® technology has now been granted in Europe. The European patent, number 2134357, granted by the European Patent Office, covers Scancell's DNA ImmunoBody® platform technology and is key to the protection of the Company's pipeline of ImmunoBody® vaccines, including lead candidates, SCIB1 and SCIB2. On issuance, this patent will extend coverage of Scancell's intellectual property into another important market for Scancell. Counterparts to this patent have already been granted in the United States, Australia and Japan.

SCIB2 lung cancer vaccine

During the year the Company announced a collaboration partnership with the Addario Lung Cancer Medical Institute (ALCMI) and the Bonnie J. Addario Lung Cancer Foundation (ALCF) to evaluate the use of Scancell's second innovative cancer vaccine, SCIB2, from its ImmunoBody® platform to treat non-small cell lung cancer (NSCLC).

The Addario Advanced Collaboration Program brings patients into clinical trials from ALCMI's extensive research consortium of international researchers and member institutions and ALCF's patient support programmes. ALCMI plans to assist Scancell in the design and development of a Phase 1/2 clinical trial with SCIB2 in patients with NSCLC in the US.

Moditope®

Scancell's Moditope® technology is a novel vaccine platform that targets neo-epitopes to overcome immune suppression induced by tumour cells. This is achieved by stimulating the production of CD4+ T cells using citrullinated tumour-associated peptide epitopes which overcome self-tolerance and destroy tumour cells. Pre-clinical studies have shown unprecedented anti-tumour effects can be delivered without requiring checkpoint inhibition.

Modi-1

Modi-1 consists of two citrullinated vimentin peptides and one citrullinated enolase peptide. Vimentin and enolase peptides are highly expressed in triple negative breast cancer, ovarian cancer and sarcoma. Preclinical data suggests that Modi-1 should be effective in up to 90% of patients with triple negative breast cancer, up to 95% of patients with ovarian cancer and up to 100% of patients with sarcoma. The Company has recently made substantial progress on the identification of an ultra-efficient adjuvant for Modi-1. This adjuvant, which will be covalently linked to the Moditope® peptides before injection, stimulates potent cancer killing T cells at up to 100-fold lower doses than could be achieved previously. The Company is currently undertaking process development work on the manufacture of Modi-1 conjugated to the adjuvant with the aim of filing a CTA in the UK for the planned Phase 1/2 clinical trial in 2018.

The response from the European patent office on the claims for the Moditope® platform suggests that very broad IP protection for the use of citrullinated peptides for the treatment of cancer is likely.

The Company is continuing discussions on potential commercial partnerships for the Moditope® platform alongside its clinical development plans, with multiple partnering discussions in progress.



Financial

Profit and Loss Account

Scancell made an operating loss for the year to 30 April 2017 of £4,548,836 (2016: loss of £3,043,163). There has been a 38% increase in development expenditure to £2,766,098 (2016: £2,009,046) and a 72% increase in administrative expenditure to £1,782,738 (2016: £1,034,117). The major items contributing to the increase in development expenditure are an increase in salary costs as headcount has increased from 9 to 11 together with the cost of manufacturing the new SCIB1 vaccine. The rise in administration expenses is due to changes in management structure including additional rental and set up costs for the Oxford and San Diego offices and a significant increase in expenditure on patents for both the ImmunoBody® and Moditope® platforms.

Overall the loss for the year was £3,544,979 (2016: loss £2,583,273).

Balance Sheet

The cash at bank at 30 April 2017 was £2,672,335 (30 April 2016: £6,527,435) and net assets amounted to £6,499,325 (30 April 2016: £9,992,281).

Share Capital Placing

On 11 May 2017, the Company placed 50,499,999 ordinary 0.1p shares at a price of 10p per share and raised £4.7m net of costs. Together with our existing cash resources and anticipated R&D tax credits, these funds will be used for: the manufacture and clinical development of Modi-1 in sarcomas, breast and ovarian cancers in a Phase 1/2 study; the filing and approval of US IND for SCIB1 checkpoint combination Phase 2 study in melanoma; further development of the product pipeline; and to support working capital requirements, which could add significant incremental value and support the Company's on-going commercial discussions.

Staff

The Board recognises that the progress made over the year would not have been possible without the dedication and support of all our staff and, on behalf of the directors, I offer our thanks to them.

Outlook

The Company has recently published robust survival data for SCIB1 showing median observation times in excess of five years in resected patients. These results, together with a successful IND submission to the FDA, will put the Company in a good position to embark upon a US Phase 2 study of SCIB1 in combination with a checkpoint inhibitor. The commencement of such a study is dependent upon the timing and outcome of the IND submission plus the Company's ability to raise sufficient funds to enable the study to be fully funded.

There has been substantial interest in Scancell's SCIB2 product for the treatment of NSCLC. We have already announced a collaboration partnership with the Addario Foundation and we are actively negotiating with other interested parties on development and commercial partnership opportunities.

The Moditope® platform continues to deliver outstanding results as we expand the number of targets under evaluation and prepare for our first clinical trial with Modi-1.

The Company has made further significant progress during the course of the past year on our pipeline of three products (SCIB1, SCIB2, Modi-1). The successful interim fundraising in May 2017 allowed the Company to continue to invest in its product pipeline whilst continuing to explore with its advisers a number of funding options to ensure that the Company has the resources to progress these programmes further. The Board believes that further funding could be best achieved following the execution of a further partnership on the ImmunoBody® or Moditope® platform.

John Chiplin Chairman



CONSOLIDATED PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME STATEMENT for the year ended 30 April 2017	2017 £	2016 £
Development expenses	(2,766,098)	(2,009,046)
Administrative expenses	(1,782,738)	(1,034,117)
OPERATING LOSS (note 2)	(4,548,836)	(3,043,163)
Interest receivable and similar income	53,445	13,522
LOSS BEFORE TAXATION	(4,495,391)	(3,029,611)
Taxation (note 3)	950,412	446,338
LOSS AND TOTAL COMPREHENSIVE INCOME FOR THE YEAR	(3,544,979)	(2,583,273)
EARNINGS PER ORDINARY SHARE (pence) (note 4) <i>Continuing operations</i> Basic	(1.36)p	(1.14)p
Diluted	(1.36)p	(1.14)p (1.14)p
Director	(1.50)p	(י-י-י)ף



CONSOLIDATED STATEMENT OF CHANGES IN EQUITY for the year ended 30 April 2017

	Share Capital £	Share Premium £	Share Option £	Retained Earnings £	Total £
Balance 30 April 2015	224,951	16,036,276	613,726	(10,120,951)	6,754,002
Share issue Expenses of issue Loss for the year Share option charge	36,607	6,186,653 (437,634)	35,926	(2,583,273)	6,223,260 (437,634) (2,583,273) 35,926
Balance 30 April 2016	261,558	21,785,295	649,652	(12,704,224)	9,992,281
Loss for the year Share option charge			52,023	(3,544,979)	(3,544,979) 52,023
Balance 30 April 2017	261,558	21,785,295	701,675	(16,249,203)	6,499,325



CONSOLIDATED STATEMENT OF FINANCIAL POSITION as at 30 April 2017

ASSETS	2017 £	2016 £
<u>Non-current assets</u> Plant and machinery Goodwill	93,109 3,415,120	64,611 3,415,120
	3,508,229	3,479,731
<u>Current assets</u> Trade and other receivables Tax receivables Cash and cash equivalents	101,803 748,837 2,672,335	120,765 440,001 6,527,435
	3,522,975	7,088,201
TOTAL ASSETS	7,031,204	10,567,932
LIABILITIES <u>Current Liabilities</u>		
Trade and other payables	(531,879)	(575,651)
TOTAL LIABILITIES	(531,879)	(575,651)
NET ASSETS	6,499,325	9,992,281
SHAREHOLDERS' EQUITY Called up share capital Share premium Share option reserve Profit and loss account	261,558 21,785,295 701,675 (16,249,203)	649,652
TOTAL SHAREHOLDERS' EQUITY	6,499,325 	9,992,281



CONSOLIDATED CASH FLOW STATEMENT for the year ended 30 April 2017

	2017 £	2016 £
Operating activities	L	L
Cash generated from operations Income taxes received	(4,489,042) 641,576	(2,997,585) 666,841
Net cash from operating activities	(3,847,466)	(2,330,744)
Investing activities		
Grant monies Asset Acquisition Other income	- (61,079) 47,060	9,776
Finance income	6,385	3,776
Net cash used by investing activities	(7,634)	13,552
Financing activities		
Proceeds from issue of share capital Expenses of share issue	-	6,223,260 (437,634)
Net cash generated from financing activities	-	5,785,626
Net increase in cash and cash equivalents	(3,855,100)	3,468,434
Cash and cash equivalents at beginning of the year	6,527,435	3,059,001
Cash and cash equivalents at end of the year	2,672,335	6,527,435



NOTES TO THE FINANCIAL INFORMATION For the year ended 30 April 2017

1 BASIS OF PREPARATION

These financial results do not comprise statutory accounts for the year ended 30 April 2017 within the meaning of Section 434 of the Companies Act 2006. The financial information in this announcement has been extracted from the audited financial statements for the year ended 30 April 2017.

The financial statements have been prepared on the going concern basis on the grounds that the directors have reviewed the funding available and the group's cash flow forecast and are content that sufficient resources are available to enable the group to continue in operation for at least twelve months from the date of approval of these accounts.

The financial information has been prepared in accordance with International Financial Reporting Standards ('IFRS'), as adopted by the European Union, and with those parts of the Companies Act 2006 applicable to companies reporting under IFRS.

The financial statements have been prepared under the historical cost convention and in accordance with applicable accounting standards.

2017

2016

2 OPERATING LOSS

3

	2017	2016
	£	£
Operating Loss is stated after charging/(crediting):		
Depreciation on tangible fixed assets	32,581	21,893
Operating lease rentals	50,580	12,500
Research and development	2,766,098	2,009,046
Auditors' remuneration – fee payable for audit of the company	8,250	8,250
Auditors' remuneration – fee payable for audit of the subsidiary	44.000	40 775
company	11,000	10,775
Auditors' remuneration for non-audit services	1,500	1,500
Directors' remuneration	543,382	330,448
TAXATION		
Analysis of the tax credit		
The tax credit on the loss on ordinary activities for the year was as		
follows:	2017	2016
Current tax	£	£
UK corporation tax credits due on R&D expenditure	748,837	440,001
Adjustment to prior year	201,575	6,337
	950,412	446,338
	350,412	440,000
Factors affecting the tax charge		
The tax assessed for the years is lower than the applicable rate of co	prooration tax in	the UK.
The difference is explained below:		
· · · · · · · · · · · · · · · · · · ·	2017	2016
	£	£
Loss on ordinary activities before tax	(4,495,391)	(3,029,611)
	(4,400,001)	(0,020,011)
Loss on ordinary activities multiplied by the small company rate of		
tax in the UK (19.92%/20%)	(895,482)	(605,922)
Effects of:		
Disallowed expenditure	10,363	8,733
Timing differences	(6,465)	7,777
Enhanced tax relief on R&D expenditure	(581,466)	(343,593)
Reduced tax relief for losses surrendered for R&D tax credits	279,910	166,897
Prior year under provision	(201,575)	(6,337)
Unrelieved losses carried forward	444,302	326,107
Current tax (credit)	(950,412)	(446,338)
		(110,000)



The Group has tax losses to carry forward against future profits of approximately £12,808,000 (2016: £11,180,000).

A deferred tax asset has not been recognised in respect of these losses as the Group does not anticipate sufficient taxable profits to arise in the foreseeable future to fully utilise them.

The estimated value of the deferred tax asset not recognised measured at the prevailing rate of tax when the timing differences are expected to reverse is £2,164,000 (2016: £1,888,000).

4 EARNINGS PER SHARE

Basic earnings per share

The earnings and weighted average number of ordinary shares used in the calculation of basic earnings per share is as follows:

	2017	2016
Earnings used in the calculation of basic earnings per share	<u>(3,544,979)</u>	(<u>2,583,273</u>)
	<u>Number</u>	<u>Number</u>
Weighted average number of ordinary shares of 0.1p each for the calculation of basic earnings per share	<u>261,558,099</u>	<u>227,558,335</u>

Diluted earnings per share

As the Group is reporting a loss from continuing operations for both years then, in accordance with IAS33, the share options are not considered dilutive because the exercise of the share options would have the effect of reducing the loss per share.

On 11 May 2017, the Company issued a further 50,499,999 ordinary shares which increased the number of shares in issue to 312,058,098.

5 DELIVERY OF ACCOUNTS

The audited statutory accounts in respect of the prior year ended 30 April 2016 have been delivered to the Registrar of Companies. The auditors issued an unqualified audit opinion which did not contain any statement under section 498(2) or 498(3) of the Companies Act 2006.

6 AVAILABILITY OF ACCOUNTS

This announcement is not being posted to shareholders. Copies of this announcement can be downloaded from the Company's website: <u>www.scancell.co.uk</u> together with copies of the Report and Accounts.